REMARKS

I. Claim Status

Claims 3-8 are currently pending. Claims 3 and 4 have been amended herein. Those claim amendments are supported in the specification as originally filed at, for example, page 4, lines 1-3 and page 5, line 29-30. Claims 5-8 have been added herein. Those claims are supported throughout the specification. Specifically, they find support on page 4, lines 15-19; page 5, lines 5-10, and page 4, line 11. Accordingly, no new matter is added herein.

III. Rejection under 35 U.S.C. § 102(b)

Claims 3 and 4 have been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Pagel et al. "Pharmacology of Levosimendan: A New Myofilament Calcium Sensititzer" *Cardiovasular Drug Reviews* (1996) 14(3):286-316 ("Pagel"). Office Action at 2. Applicants respectfully disagree with this rejection and assert that it does not apply to the presently pending claims.

Applicants submit herewith an Information Disclosure Statement that cites the poster abstract underlying the studies reported in Pagel on which the Examiner relies. *See* Pagel at 304, ref. 54. For the purposes of responding to the present rejection, Applicants will make reference to both Pagel and that document: Sandell, E. P., et al. "The Effects of Renal Failure on the Pharmacokinetics of Levosimendan," *Therapie* (Suppl 1) (1995) 50:S495 ("Sandell").

Applicants respectfully assert that Pagel and Sandell do not expressly anticipate the presently pending claims. In particular, currently pending independent claims 3 and 4 include limitations regarding the dosing schedule of levosimendan and its metabolite: "said method comprising administering ***daily or periodically***." Sandell and Pagel do

not disclose that ^{14}C-labeled levosimendan was administered more than one time.[1] In fact, Sandell reports only that ^{14}C-labeled levosimendan was administered in one dose for the purpose of determining the pharmacokinetics of levosimendan in patients with compromised renal function. Consequently, Pagel and Sandell do not expressly anticipate the present claims.

Applicants respectfully assert that Pagel and Sandell likewise do not inherently anticipate the presently pending claims. According to the Federal Circuit, the fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531 (Fed. Cir. 1993) (reversing rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art); *see also* M.P.E.P. § 2112. The Examiner concedes that Pagel does "not teach that this method treats renal failure or reduces the mortality of the patients." Office Action at 2-3. Furthermore, as discussed above, neither Pagel nor Sandell teach administering levosimendan or its metabolite more than once to a renal failure patient.

[1] Applicants note that Sandell concludes that "on the basis of pharmacokinetics levosimendan may be used in similar doses in patients with mild to moderate renal failure and in subjects with normal renal function." This conclusion does not expressly anticipate the present claims, nor does it inherently anticipate the present claims. Those authors were simply speculating regarding the dose tolerance in renal failure patients for using levosimendan for its known cardiotonic drug properties, i.e., the authors were suggesting that patients requiring levosimendan, who also happened to be in mild to moderate renal failure, would likely tolerate similar doses. Furthermore, this conclusion does not enable one of ordinary skill in the art to practice the presently claimed methods.

Because Sandell and Pagel do not expressly or inherently anticipate the present claims and, as the Examiner notes, one of skill in the art would not recognize the treatment value of levosimendan or its metabolite for renal failure, the presently pending claims are likewise not obvious over either Pagel or Sandell. As the M.P.E.P. points out "[o]bviousness cannot be predicated on what is not known at the time an invention was made, even if the inherency of a certain feature is later established." M.P.E.P. § 2141.02.V. Properties that "may be inherent [are] not necessarily known. Obviousness cannot be predicated on what is unknown." *In re Shetty*, 566 F.2d 81, 86, 195 U.S.P.Q. 753, 757, (C.C.P.A. 1977), quoting *In re Spormann*, 363 F.2d 444, 448, 150 U.S.P.Q. 449, 452 (C.C.P.A. 1966). Following this Federal Circuit precedence, no *prima facie* case of obviousness over Pagel or Sandell could be made.

CONCLUSION

In view of the foregoing remarks and documents submitted herewith, Applicants respectfully request reconsideration of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

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